



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner

: L. Helms

Group Art Unit

1615

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:

Applicants

Bhami Shenoy et al.

Application No.

10/034,950

Confirmation No.: 9344

Filed

: December 26, 2001

For

CRYSTALS OF WHOLE ANTIBODIES AND FRAGMENTS THEREOF AND METHODS FOR

MAKING AND USING THEM

New York, New York

June 27, 2003

Hon. Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure
Statement in the above-identified application. This
Statement is submitted:

- [] within three months of the application filing date;
- [X] more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge

payment of any fees required in connection with this
Information Disclosure Statement to Deposit Account
No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

Margaret A. Pierri (Reg. No. 30,709)

Attorney for Applicants

Andrew K. Holmes (Reg. No. 51,813)

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I hereby certify that this Correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope Addressed to: Commissioner for Patents P.O. Box 1450

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Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants, through their representatives, hereby make of record the documents listed in the accompanying Form PTO-1449, enclosed herewith in duplicate. Copies of these documents are enclosed.

UNITED STATES PATENTS

Johal, U.S. Patent 4,334,024 (6/8/82);
Bosch et al., U.S. Patent 5,510,118 (4/23/96);
Eckenhoff et al., U.S. Patent 5,904,935 (5/18/99);
Navia et al., U.S. Patent 6,011,001 (1/4/00);
Khalaf, U.S. Patent 6,042,824 (3/28/00); and
Margolin et al., U.S. Patent 6,140,475 (10/31/00).

FOREIGN APPLICATIONS

PCT Publication WO 91/09943, published July 11, 1991 PCT Publication WO 96/40049, published December 19, 1996 PCT Publication WO 99/55310, published November 4, 1999 PCT Publication WO 00/52150, published September 8, 2000

OTHER DOCUMENTS

Baselga et al., "Recombinant Humanized Anti-HER2 Antibody (Herceptin) Enhances the Antitumor Activity of Paclitaxel and Doxorubicin against HER2/neu Overexpressing Human Breast Cancer Xenografts," Cancer Res, Volume 58, pp. 2825-31 (1998).

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Pichla et al. "The Crystal Structure of a Fab Fragment to the Melanoma-Associated GD2 Ganglioside," <u>J. Struct.</u> <u>Biol.</u>, Volume 119, pp. 6-16 (1997).

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Pikal et al., "The Stability of Insulin in Crystalline and Amorphous Solids: Observation of Greater Stability for the Amorphous Form," <u>Pharm. Res.</u>, Volume 14, pp. 1379-87 (1997).

Rodgers, "Practical Cryocrystallography," <u>Methods in Enzymology</u>," Volume 276, pp. 183-203 (1997).

Saul et al., "Structure of the Fab fragment from F124, a monoclonal antibody specific for hepatitis B surface antigen," Acta. Crystallogr. D. Biol. Crystallogr., Volume D56, pp. 945-951 (2000).

Shenoy et al., "Stability of Crystalline Proteins, Biotechnol. Bioeng., Volume 73, pp. 358-69 (2001).

Sohi et al., "Crystallization and Preliminary X-ray Analysis of the Fab Fragment of a Human Monoclonal IgM Rheumatoid Factor (2A2)," <u>J. Mol. Biol.</u>, Volume 242, pp. 706-08 (1994).

Sullivan et al., "Sustained release of progesterone and estradiol from the SABER™ delivery system: In vitro and in vivo release rates," <u>Proceed. Int'l. Symp. Control.</u> Rel. Bioact. Mater., Volume 25, pp. 653-54 (1998).

Yoshino, "Treatment with an Anti-IL-4 Monoclonal Antibody Blocks Suppression of Collagen-Induced Arthritis in Mice by Oral Administration of Type II Collagen," <u>J. Immunol.</u>, Volume 160, pp. 3067-3071 (1998).

It is respectfully requested that the enclosed documents be (1) fully considered by the Examiner during the examination of this application; and (2) printed on any patent which may issue on this application. Applicants request that a copy of Form PTO-1449, as considered and initialed by the Examiner, be returned with the next communication.

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JUNE 27, 2003 Lillian Garcia

Signature of Person Signing

Respectfully submitted,

Margaret A. Pierri (Reg. No. 30,709)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO.	APPLICATION
VPI/00-08	NO. 10/034,950
APPLICANT	CONF. NO.
Shenoy et al.	9344
FILING DATE	GROUP
December 26, 2001	1615

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,334,024	6/8/82	Johai	435	232	
	5,510,118	4/23/96	Bosch et al.	424	489	RECEIVED
	5,904,935	5/18/99	Eckenhoff et al.	424	489	444
	6,011,001	1/4/00	Navia et al.	514	2	JUL 0 7 2003
	6,042,824	3/28/00	Khalaf	424	94.6	TECH CENTER 1600/2900
	6,140,475	10/31/00	Margolin et al.	530	402	7000/2900

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 91/09943	7/11/91	PCT	C12N	9/98		
	WO 96/40049	12/19/96	PCT	A61K	9/00		
	WO 99/55310	11/4/99	PCT	A61K	9/86		
	WO 00/52150	9/8/2000	PCT	C12N	7/00		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
	Baselga et al., "Recombinant Humanized Anti-HER2 Antibody (Herceptin) Enhances the Antitumor Activity of Paclitaxel and Doxorubicin against HER2/neu Overexpressing Human Breast Cancer Xenografts," Cancer Res, Volume 58, pp. 2825-31 (1998).
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) **EXAMINER** INITIAL Harris et al., "Comparison of the conformations of two intact monoclonal antibodies with hinges," Immunol. Rev., Volume 163, pp. 35-43 (1998) Harris et al., "Crystallographic Structure of an Intact IgG1 Monoclonal Antibody," J. Mol. Biol., Volume 275, pp. 861-872 (1998). Ito, et al., "Crystallization and preliminary X-ray crystallographic studies on a Fab fragment of the mouse anti-human Fas monoclonal antibody HFE7A," Acta. Crystallogr. D. Biol. Crystallogr., Volume D57, pp. 1700-1702 (2001). Kim et al., "Gene therapy for established murine collagen-induced arthritis by local and systemic adenovirus-mediated delivery of interleukin-4," Arthritis Res., Volume 2, pp. 293-302 (2000). Küttner et al., "A phage library-derived single-chain Fy fragment in complex with turkey egg-white lysozyme: characterization, crystallization and preliminary X-ray analysis," Molecular Immunology, Volume 35, pp. 189-194 (1998). Malfait et al., "Chronic Relapsing Homologous Collagen-Induced Arthritis in DBA/1 Mice as a Model for Testing Disease-Modifying and Remission-Inducing Therapies," Arthritis Rheum., Volume 44, pp. 1215-24 (2001). McPherson, "Preliminary Analysis: Mounting and aligning procedures," in Preparation and Analysis of Protein Crystals, pp. 214-27 (John Wiley & Sons Publishing) (1989). Mylvaganam et al., "Structural Basis for the Binding of an Anti-cytochrome c Antibody to its Antigen: Crystal Structures of FabE8-Cytochrome c Complex to 1.8 Å Resolution and FabE8 to 2.26 Å Resolution," J. Mol. Biol., Volume 281, pp. 301-22(1998). Pekarek et al., "Double-walled polymer microspheres for controlled drug release," Nature, Volume 367, pp. 258-60 (1994). Pichla et al. "The Crystal Structure of a Fab Fragment to the Melanoma-Associated GD2 Ganglioside," J. Struct. Biol., Volume 119, pp. 6-16 (1997). Pietras et al., "Monoclonal Antibody to HER-2/neu Receptor Modulates Repair of Radiation-induced DNA Damage and Enhances Radiosensitivity of Human Breast Cancer Cells Overexpressing This Oncogene," Cancer Research, Volume 59, pp. 1347-1355 (1999). Pikal et al., "Quantitative Crystallinity Determinations for β-Lactam Antibiotics by Solution Calorimetry: Correlations with Stability," J. Pharm. Sci., Volume 67, pp. 767-73 (1978). Pikal et al., "The Stability of Insulin in Crystalline and Amorphous Solids: Observation of Greater Stability for the Amorphous Form," Pharm, Res., Volume 14, pp. 1379-87 (1997). Rodgers, "Practical Cryocrystallography," Methods in Enzymology," Volume 276, pp. 183-203 (1997). Saul et al., "Structure of the Fab fragment from F124, a monoclonal antibody specific for hepatitis B surface antigen," Acta. Crystallogr. D. Biol. Crystallogr., Volume D56, pp. 945-951 (2000). Shenoy et al., "Stability of Crystalline Proteins," Biotechnol. Bioeng., Volume 73, pp. 358-69 (2001). Sohi et al., "Crystallization and Preliminary X-ray Analysis of the Fab Fragment of a Human Monoclonal IgM Rheumatoid Factor (2A2)," J. Mol. Biol., Volume 242, pp. 706-08 (1994). Sullivan et al.. "Sustained release of progesterone and estradiol from the SABER™ delivery system: In vitro and in vivo release rates," Proceed. Int'l. Symp. Control. Rel. Bioact. Mater., Volume 25, pp. 653-54

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Sheet 3 of 3

OTHER DOCUMENTS	(Including Author.	Title, Date.	Pertinent Pages	Etc.)
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